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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | | ATTORNEY DOCKET NO. |
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| 09/157,289 | 09/18/98 | ASHKENAZI | A | 11669.31US03 |

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| EXAMINER | |
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| KAUFMAN, C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | 18 |

**DATE MAILED:** 03/23/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/157,289 | Applicant(s) Ashkenazi et al. |
|---|---|---|
| | Examiner Prema Mertz | Group Art Unit 1646 |

☒ Responsive to communication(s) filed on *Feb 15, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-66* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-66* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 40-48, 66, 9-13, drawn to a nucleic acid molecule encoding DcR3 polypeptide, a vector, a host cell, a method of making the DcR3 polypeptide and a chimeric protein comprising the DcR3 polypeptide, classified in Class 435, subclass 69.1.

II. Claims 1-8, 53, 55*, 56*, drawn to a DcR3 polypeptide, classified in Class 530, subclass 350.

III. Claims 14-39, 54, 55*, 56*, drawn to an antibody which binds DcR3 polypeptide, classified in Class 530, subclass 387.9.

IV. Claims 49-50, drawn to a non-human transgenic animal comprising a nucleic acid encoding the DcR3 polypeptide, classified in Class 800, subclass 14.

V. Claims 51-52, drawn to a non-human knockout animal comprising an altered gene encoding the DcR3 polypeptide, classified in Class 800, subclass 14.

VI. Claims 57-59 and 65, drawn to a method of modulating apoptosis in mammalian cells by administering the DcR3 polypeptide, classified in Class 514, subclass 2.

VII. Claims 60-63, drawn to a method of treating mammalian cancer by exposing cells to DcR3 antibodies, classified in Class 424, subclass 139.1.

VIII. Claim 64, drawn to a method of detecting or diagnosing cancer by analyzing mammalian cells for amplification of a DcR3 gene, classified in Class 435, subclass 6.

*These claims embrace multiple patentably distinct embodiments, DcR3 polypeptide and antibody to DcR3 polypeptide.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV-V, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of invention I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of invention II can be used as a probe, or used therapeutically or diagnostically, e.g. in screening. The antibody of invention III can be used to obtain the nucleic acid of Group I, and can also be used in diagnostics, e.g. as a probe in immunoassays. Inventions IV-V are independent and distinct from each other because they clearly do not have similar properties. A transgenic animal and a knock-out animal are mutually exclusive products, encompass different subject matter, have different properties and do not share a common technical feature. There is no common search for the transgenic animal (overexpression of the gene of interest) and the knock-out animal (altered gene of interest expressed).

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be

prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. nucleic acid, as claimed can be used in gene therapy or in production of the protein encoded by the nucleic acid.

Inventions II and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention II can also be used as an antigen in the production of antibodies.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention III can also be used as a probe in immunoassays or in immunoaffinitychromatography.

Inventions I and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and VII-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions III and VI, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VI-VIII, are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
March 21, 2000